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MARY HELEN SEARS
M.H. SEARS LAW FIRM, CHTD.
Suite 800
910 Seventeenth Street, N.W.
Washington, DC 20006

EXAMINER	
MUI, CHRISTINE T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,461	GUPTA, SURENDRA K.	
	Examiner	Art Unit	
	Christine T. Mui	1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, it is unclear to the examiner where it states, "measured by a device comprised of at least one light emitting diode and at least one light detector in the range between 360 and 880 nm wavelength." It is unclear if the device to measure the signal produced is part of the claimed invention or a means to measure to color in a visible color range.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-4 and 6-13 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,238,652 to Sun et al. (herein referred "Sun").

Regarding claim 1, the reference Sun discloses analytical test devices for the competition assay for drugs of non-protein antigens. The analytical test devices disclosed are in a multiple test configuration with three test devices (arms) in a single holder that share a common reception area cavity where the liquid test sample is introduced to the reception cavity through a central opening. The test strips contain specific analyte-conjugate probe and corresponding antibody coated on latex particles. The strip are placed in the holder in a symmetrical pattern and individually marked for each specific test (see column 9, lines 33-34 and 36-42; Figure 7a-7c and 8a-8c). Six test devices with a common reception cavity can also represent a multiple test configuration (see column 9, lines 60 and 65).

Regarding claims 3-4 and 6-7, the reference Sun discloses the samples that can be added to the reception cavity only require a few drops of urine, biological fluids (saliva) or aqueous solutions (environmental water; swimming pool water or fish tank water) (see column 2, lines 46-48).

Regarding claims 8-10, the reference Sun discloses an embodiment of the device to have a chromatographic membrane suspended in the chamber of the device and when a sample is deposited, the solution percolates through an absorbing or filter pad (filter paper) onto the membrane below (see column 8, line 52-53 and 56-59; Figure 4a-4k).

Regarding claim 11, the reference Sun disclosed multiple test configurations where there are three or six test devices (arms) on a single holder (see column 9, lines 33 and 60; Figures 7a-7c and 8a-8c).

Regarding claims 12-13, the reference Sun discloses analytical test devices where there are latex spheres detecting non-protein antigens in the sample by indicating the absence or present of a colored line or indication in the area of the drug conjugate probe. The appearance of a colored line indicates the presence of a complex made up of the protein antigen on the latex spheres (see column 6, lines 44-48 and 50- 53).

3. Claim 1-3, 5-6, 8-9, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,707,818 to Chudzik et al. (herein referred "Chudzik").

Regarding claim 1, the reference Chudzik discloses a device to simultaneously performing multiple competitive immunoassays having a center well where the sample is added that migrate along paths (arms) and readout in four directions (see column 6, lines 59-60 and 63-65). The device has flow paths that further comprise of a plurality of respective reagent zones downstream from the origin and each reagent zone of each immunoassay prove the reagents necessary for performing a visual read out (see column 5, lines 4-8).

Regarding claims 2-3 and 5-6, the reference Chudzik discloses the samples to be used with the device preferably are an aqueous solution obtained directly from the source (e.g., urine or blood), a non-aqueous sample by mixing or extracting (e.g., tissue) (serum or plasma) and an extraction of contaminants in meat or seafood (food) or pollutants in soil samples or the analysis or ground water for contaminants and the

analysis of agricultural products (see column 4, lines 17-20, 23-24 and 37-38). The device is also able to detect drugs such as marijuana, cocaine, morphine, morphine glucuronide, amphetamine and methamphetamine (see column 7, line 15-19).

Regarding claims 8-9, the reference Chudzik discloses the material used in the device can be made of nitrocellulose membranes, nylon membranes or other commercially available membrane and can be made of porous material made from natural polymeric material particularly cellulosic material such as filter paper (see column 4, lines 45-47 and 53-54).

Regarding claim 11, the reference Chudzik discloses the device is able to have one or more flow paths (see column 2, line 31) and is shown in Figure 1 to have four flow paths (see column 6, line 59-60).

Regarding claims 12-13, the reference Chudzik discloses the device has indicator window that changes color when the reaction is complete (see column 6, lines 64-65). The analyte conjugate in the device are in the form of a label or tracer, which can be fluorescent species, dyes and colored polymeric materials (see column 5, lines 43-45). On the indicator strip used at the terminal indicator of the flow path is a pH indicator that will change color when urine is present (see column 7, lines 38-39).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik as applied to claim 2 above, and further in view of USP 6,117,630 to Reber (herein referred "Reber") and USP 6,342,349 to Virtanen (herein referred "Virtanen").

Regarding claim 14, the reference Chudzik discloses the claimed invention except for measuring the analytes of cholesterol and glucose. Reber teaches that it is known to have devices that detect the glucose level in blood (see column 1, line 52-54). Virtanen teaches that it is known to have devices that detect cholesterol in samples (see column 2, line 7; Table 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the detection device of multiple analytes to detect different aspects of blood.

9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik as applied to claim 3 above, and further in view of USP 4,069,016 to Wu (herein referred "Wu")

Regarding claim 23, the reference Chudzik discloses the claimed invention except for measuring the analyte of glucose. Chudzik discloses the analyte detector device able to indicate pH (see column 7, lines 38-39). Wu teaches an assay element that detects bilirubin in biological liquid sample such as blood, serum or urine that can be used in "dry-to-the-touch" elements such as monolayer test strip (see column 1, line 17-19 and 26-28). It would have been obvious to one having ordinary skill in the art at the time the

invention was made to construct an analyte testing device able to detect an array of different analytical elements in urine.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sun as applied to claim4 above, and further in view of USP 4,786,596 to Adams (herein referred "Adams").

Regarding claim 24, the reference Sun discloses the claimed invention except for the intended use of measuring alcohol in saliva. Sun discloses the invention using a biological sample (saliva) to measure the presence of drugs in particular, amphetamines/methamphetamines, cocaine, opiates, phencyclidine and cannabinoids (see column 2, lines 50-54). Adams teaches that it is known to used a test strip or stick with a carrier matrix used to test human saliva for traces of ethanol and change color with the presence of alcohol (see column 1, lines 7-8 and column 5, line 19-20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct an analyte testing device with a matrix that indicates barbiturates and alcohol in saliva by impregnating the testing pad or matrix with an array of different conjugates or enzymes to indicate is certain species are present in a sample to expand the array of species a testing device can detect.

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik as applied to claim 5 above, and further in view of USP 5,605,838 to Backhaus (herein referred "Backhaus").

Regarding claim 25, the reference Sun discloses the claimed invention except for the intended use of measuring glucose, proteins and lipids in food. Backhaus teaches that it is known in the art to have a sample carrier with an absorbent stamp to measure analytes including glucose, proteins, hormones, glycerides and lipids in foods and liquids including blood, plasma, serum, urine and saliva (see column 3, line 28, 31-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct testing device to detect different species in food to indicate their presence.

12. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik as applied to claim6 above, and further in view of USP 5,811, 254 to Wu (herein referred "#254).

Regarding claim 26, the reference Sun discloses the claimed invention except for the intended use of measuring total chlorine, free chlorine or pH in a sample of water. #254 teaches that is known to have a test device that includes a test pad with a suitable carrier matrix incorporating an indicator reagent composition capable of converting combined available chlorine to free available chlorine to determine the total available

chlorine concentration in a sample. (see column 3, lines 45-51). The reagent includes an indicator capable of interacting with free available chlorine to provide a detectable and measurable response in a sufficient color differentiation between the samples (see column 3, line 64-65 and column 4, line 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct test device to measure the amount of free and total chlorine in a water sample such as swimming pool water to ensure proper levels of chlorine are present.

13. Claims 27-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun as applied to claim 1 above.

Claims 27-35 and 38 are directed to intended use of the analyte detector device and not a limitation of the device as claimed. The devices the Sun reference discloses is able to use many samples including urine, biological fluids (which can include blood, plasma, serum or saliva) as well as aqueous solutions which use latex spheres that are coated with a detecting antibody for the antigen of interest (see column 2, lines 47-48 and column 6, line 15-16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the latex spheres the test device will be able to detect the claimed disease and disorders.

14. Claims 14-22, 27-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik as applied to claims 1 and 2 above.

Claims 14-22, 27-35 and 38 are directed to intended use of the analyte detector device and not a limitation of the device as claimed. The device that Chudzik discloses able to use blood as a sample and each reagent zone in the flow path have the necessary reagents for performing a visual read-out and a receptor in recognizing a particular spatial and polar organization of the analyte of interest. The receptors include antibodies, enzymes, lectins and the like (see column 5, line 4-8 and 21-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the reagents in the visual read-out zone, the test device is capable of detecting the claimed diseases and disorders.

15. Claim 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudzik as applied to claim1 above, and further in view of USP 6,524,864 to Decastro (herein referred "Decastro").

Chudzik teaches the claimed invention except for obtaining the sample as a capillary blood from a finger, heel or earlobe. Decastro teaches that it is known to obtain a sample of blood from venous or capillary blood from a finger stick or a heel stick (see column 2, line 27-29) to be used in a test strip capable of running several color tests simultaneously using serum plasma or whole blood (see column 1, lines 6-8). It would have been obvious to one having ordinary skill in the art at the time the invention was

made to obtain the sample of blood form capillary blood from finger or heel stick because it is convenient to obtain, user friendly and able to leave minimal puncture size wounds.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP 5,981,298 to Chudzik; WO 96/18904 to Chudzik; USP 5,202,261 to Musho; USP 5,620,900 to Tanzer .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine T. Mui whose telephone number is (571) 270-3243. The examiner can normally be reached on Monday-Friday 8-5; Alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

Walter D. Griffin

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER